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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Buechler, et al.

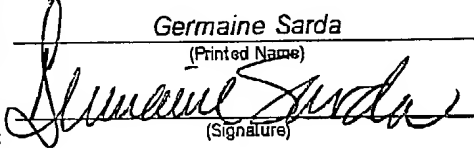
Title: NOVEL METHODS FOR THE ASSAY
OF TROPONIN I AND T AND
COMPLEXES OF TROPONIN I AND T
AND SELECTION OF ANTIBODIES
FOR USE IN IMMUNOASSAYS

Appl. No.: 09/349,194

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Examiner: Gailene Gabel

Art Unit: 1641

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TRANSMITTALCommissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed please find the following:

- [X] Appendix A: Clean Copy Text of the Claims as Amended in Submission Dated
07/07/2003 (14 Pages).

Respectfully submitted,

Date November 29, 2004By Barry S. WilsonFOLEY & LARDNER LLP
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*Appendix A: Clean Copy Text of the Claims as Amended in Submission Dated July 7, 2003
(claims identified as "previously amended" were amended on July 7, 2003)*

1-84 (cancelled)

85. (Previously pending) An assay for determining the presence or amount of a free and complexed cardiac specific isoform of troponin in a patient sample, said assay comprising: performing an immunoassay with an antibody which specifically binds said free cardiac specific isoform of troponin, and which specifically binds said cardiac specific isoform of troponin in a binary complex comprising one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds said cardiac specific isoform of troponin in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoform of troponin, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoform of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoform of troponin; or (iii) a combination of (i) and (ii), and wherein said signal is related to the presence or amount of said free and complexed cardiac specific isoform of troponin in said sample.

86. (Previously pending) An assay according to claim 85, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

87. (Previously pending) An assay according to claim 85, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoform of troponin is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoform of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoform of troponin; or (iii) a combination of (i) and (ii).

88. (Previously pending) An assay for determining the presence or amount of free and complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin I and cardiac specific troponin T, and which specifically binds to cardiac specific troponin I and cardiac specific troponin T in a complex comprising at least one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds to cardiac specific troponin I and cardiac specific troponin T in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoforms of troponin, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoforms of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoforms of troponin; or (iii) a combination of (i) and (ii), and wherein said signal is related to the presence or amount of said free and complexed cardiac specific isoforms of troponin in said sample.

89. (Previously pending) An assay according to claim 88, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

90. (Previously pending) An assay according to claim 88, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoforms of troponin is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoforms of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoforms of troponin; or (iii) a combination of (i) and (ii).

91. (Previously pending) An assay for determining the presence or amount of free and complexed cardiac specific troponin I in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin I, and which specifically binds to cardiac specific troponin I in a complex comprising at least one other troponin component selected from the group consisting of troponin C and troponin T, and which specifically binds to cardiac specific troponin I in a ternary complex comprising troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin I, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin I; (ii) troponin complexes which do not comprise said cardiac specific troponin I; or (iii) a combination of (i) and (ii), and wherein said detectable signal is related to the presence or amount of said free and complexed cardiac specific troponin I in said sample.

92. (Previously pending) An assay according to claim 91, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

93. (Previously pending) An assay according to claim 91, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin I is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin I; (ii) troponin complexes which do not comprise said cardiac specific troponin I; or (iii) a combination of (i) and (ii).

94. (Previously pending) An assay for determining the presence or amount of free and complexed cardiac specific troponin T in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin T, and which specifically binds to cardiac specific troponin T in a complex comprising at least one other troponin component selected from the group consisting of troponin

C and troponin I, and which specifically binds to cardiac specific troponin T in a ternary complex comprising troponin C and troponin I; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin T, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin T; (ii) troponin complexes which do not comprise said cardiac specific troponin T; or (iii) a combination of (i) and (ii), and wherein said detectable signal is related to the presence or amount of said free and complexed cardiac specific troponin T in said sample.

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95. (Previously pending) An assay according to claim 94, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

96. (Previously pending) An assay according to claim 94, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin T is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin T; (ii) troponin complexes which do not comprise said cardiac specific troponin T; or (iii) a combination of (i) and (ii).

97-101 (cancelled)

102. (Previously pending) An assay for determining the presence or amount of all free and complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds all free cardiac specific isoforms of troponin, and which specifically binds all cardiac specific isoforms of troponin in a complex comprising at least one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds all cardiac

specific isoforms of troponin in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoforms of troponin, wherein said signal is related to the presence or amount of all free and complexed cardiac specific isoforms of troponin in said sample.

103. (Previously pending) An assay according to claim 102, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

104. (Previously pending) An assay according to claim 102, wherein said signal is approximately equal for equal amounts of all cardiac specific isoforms of troponin.

105. (Previously pending) An assay according to claim 102, wherein said signal is within 20% for equal amounts of all cardiac specific isoforms of troponin.

106. (Previously pending) An assay according to claim 102, wherein said signal is within a factor of 2 for equal amounts of all cardiac specific isoforms of troponin.

107-113 (cancelled)

114. (Previously pending) An assay for determining the presence or amount of a free and complexed cardiac specific isoform of troponin in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds said free cardiac specific isoform of troponin, and which specifically binds said cardiac specific isoform of troponin in a complex comprising at least one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds said cardiac

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Total # of Pages 16 (including this page)

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From : Barry S. Wilson

Date : November 29, 2004

Client/Matter No : 071949-2104

User ID No : 3067

MESSAGE:

Re: U.S. Patent Application No. 09/349,194
Our Ref.: 071949-2104

Per your request please find the enclosed documents:

- Transmittal (1 pg.);
- Appendix A: Clean Copy Text of the Claims as Amended in Submission Dated 07/07/03 (14 pgs.).

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